K021992

JAN 1 4 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Kacy Arnold, RN. MBA
Telephone: (574) 372-1644
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Proprietary Name: DHS Disposable Hood System

Common Name: Disposable Surgical Hood

Classification Name: Surgical Apparel (21 CFR 878.4040)

Legally Marketed Devices to Which Substantial Equivalence is Claimed:
- Stryker Steri-Shield Personal Protection Device
- DePuy Sterile View Disposable Hood / Gown

Device Description: The device consists of an enclosure of drape material that is worn by members of a surgical team and is fitted to the head with an adjustable headband. A clear viewing window is provided along with an air delivery system to supply cool air under the enclosure via a fan powered by a battery pack worn on the waistband.

Intended Use: The device is a sterile, single-use, personal protective system designed to provide a barrier between the surgical team and potentially hazardous body fluids that may be present in the operation room environment.

Summary of Technologies: The disposable sterile surgical hood components (materials, design, sizes and indications) are similar or identical to the predicate devices.

Non-Clinical Testing: Non-clinical testing demonstrated the device performed as well as or better than currently marketed devices. Substantial equivalence was determined based on a comparison of technological characterizes with the predicate device. This comparison included fabric weight, grab strength, grab elongation, trap tear, hydrohead test, spray impact, alcohol (repellency), permeability and static decay.

Clinical Testing: Clinical testing was not used to establish substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 4 2003

Mr. Kacy Arnold
Regulatory Affairs Specialist
Biomet Orthopedics, Incorporated
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K021992
Trade/Device Name: DHS Disposable Surgical Hood System
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: January 2, 2003
Received: January 7, 2003

Dear Mr. Arnold:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known) : K021992

Device Name: DHS Disposable Hood System

Indications for Use:

The device is a sterile, single-use, personal protective system designed to provide a barrier between the surgical team and potentially hazardous bloodborne pathogens that may be present in the operation room environment. The device also offers the patient additional protection from potential deep wound infection by preventing skin, hair and other debris entry into the wound from surgical team members

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Alice S. Lin

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K021992